

Appl. No. : 10/550,224
Filed : May 2, 2006

REMARKS

Claims 21-23 have been canceled without prejudice to or a disclaimer of the subject matter recited therein. No new matter or no new issue has been added. Applicants believe that entry of the amendment would place the application in better condition for allowance or appeal. Applicants respectfully request entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Election/Restrictions

Claims 21-23 have been withdrawn from consideration as being directed to a non-elected invention. Accordingly, Claims 21-23 are herein canceled.

Rejection of Claims 1-4, 6-10, 13-16, and 20 Under 35 U.S.C. § 103

The Office Action states that Claims 1-4, 6-10, 13-16, and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Haratake JP 2000-169328 (Haratake) in view of Candau et al. US publication 20020064507 (Candau) and further in view of Benaiges et al. Study of the refirming effect of a plant complex, International Journal of Cosmetic Science Volume 20 Issue 4 Page 223-233, August 1998 (Benaiges) in view of Sekimoto US 6814958 (Sekimoto).

However, Claims 4-6, 13, and 14 were previously canceled. Further, Claim 17 is not included in this rejection, although the first page of the Office Action indicates that Claim 17 has been rejected. Applicants assume that Claims 1-3, 7-10, 15-17, and 20 are rejected on this ground as indicated on the first page of the Office Action.

Claim 1 herein recites:

A topical composition for treating wrinkles on the skin comprising silymarin dissolved in dipropylene glycol and contained in an amount of 0.7% to 2.0% by weight effective to promote the production of type I collagen and/or to promote the production of elastin.

As defined in Claim 1, when the topical composition comprises 0.7% to 2.0% silymarin dissolved in dipropylene glycol, the topical composition effectively promotes not only the production of type I collagen and the production of elastin (e.g., Figs. 3 and 4), but also effectively penetrates the skin (e.g., Fig. 5), thereby reducing the wrinkle depth (e.g., Figs. 6 and 7), increasing skin elasticity (e.g., Fig. 8), and improving the skin conditions visually (e.g., Fig. 5) and sensuous feeling (e.g., Fig. 9). The following tables are reproduced Tables 3 and 4 on pages 18 and 19.

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Table 3: The production of type I collagen

Formulation	Concentration (%)	Relative expression level
Untreated control		1.0
Soybean lecithin	1.0	1.1
Silymarin	0.5	1.1
	0.7	2.7
	1.0	3.3
	1.5	2.4
	2.0	2.2
Retinoic acid	0.05	2.0

Table 4: The production of elastin

Formulation	Concentration (%)	Relative expression level
Untreated control		1.0
Soybean lecithin	1.0	0.9
Silymarin	0.5	0.8
	0.7	2.5
	1.0	4.3
	1.5	3.3
	2.0	2.0
Retinoic acid	0.05	3.3

Further, the following table is a reproduced table based on Fig. 5.

Table: Permeability

Formulation	Concentration (%)	Permeability (%)
Silymarin	0.5	0.7
	0.7	1.0
	1.0	1.2
	1.5	1.4
	2.0	1.6

As shown above, the topical composition which comprises 0.7% to 2.0% silymarin dissolved in dipropylene glycol effectively penetrates the skin and effectively promotes the production of type I collagen and the production of elastin.

Haratake discloses a composition containing an extract from a plant of the genus *Silybum* of the family Compositae, e.g., *Silybum marianum* called Maria-azami, O-azami or Ohire-azami in amount of 0.0001-2.0 wt% for enhancing effects on epidermal permeation barrier functions. In any predictable manner, Haratake does not provide any indication that 0.7% to 2.0% silymarin dissolved in dipropylene glycol effectively penetrates the skin and effectively promotes the production of type I collagen and the production of elastin. Further, Haratake's composition enhances epidermal permeation barrier functions and is not expected to increase skin permeability.

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Further, although Haratake fails to teach dipropylene glycol, the Examiner asserts that Candau teaches use of dipropylene glycol. However, Candau's composition is for artificially coloring the skin and contains a radiation-screening agent. Thus, in Candau, the radiation-screen agent stays on the skin and is not expected to and should not penetrate the skin. One of ordinary skill in the art could not expect from Candau that 0.7% to 2.0% silymarin dissolved in dipropylene glycol effectively penetrates the skin and effectively promotes the production of type I collagen and the production of elastin, because skin penetration would destroy the principle of functions of the radiation-screen agent in Candau.

Additionally, the radiation-screening agent in Candau and the extract from a plant of the genus *Silybum* of the family Compositae in Haratake are chemically dissimilar, and the extract from a plant of the genus *Silybum* of the family Compositae in Haratake does not require a solvent. Therefore, there is no motivation or reason to use dipropylene glycol which is used as a solvent for the radiation-screening agent in Candau, to dissolve the extract from a plant of the genus *Silybum* of the family Compositae in Haratake.

Benaiges and Sekimoto do not supply the deficiencies of Haratake and Candau. Thus, Claim 1 could not be obvious over Haratake, Candau, Benaiges and Sekimoto. Claims 2-3, 7-10, and 15-16 also could not be obvious over Haratake, Candau, Benaiges and Sekimoto due to their dependencies upon Claim 1 in addition to the other elements recited therein.

Claim 17 as amended herein recites:

A method for treating wrinkles on the skin of a subject by promoting the production elastin in an extracellular matrix of a dermis, comprising topically administering to the subject an effective amount of a composition comprising silymarin dissolved in dipropylene glycol and contained in an amount of 0.7% to 2.0% by weight.

The topical composition used in Claim 17 comprises silymarin dissolved in dipropylene glycol and can effectively penetrate the skin and effectively treat wrinkles with use in an amount of 0.7% to 2.0% by weight.

The Examiner states that although Haratake fails to teach the use of silymarin to treat wrinkles, Benaiges discloses a study of the refirming effect of a plant complex and teaches that one way to prevent such a loss of elasticity is to use active ingredients that are able to inhibit elastase enzymes. However, Benaiges does not teach or suggest that 0.7% to 2.0% silymarin dissolved in dipropylene glycol can effectively penetrate the skin and effectively treat wrinkles on

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the skin by promoting the production of elastin. As discussed above, Candau and Sekimoto do not supply the deficiencies of Haratake and Benaiges. Therefore, Claim 17 could not be obvious over Haratake, Candau, Benaiges and Sekimoto. Claim 20 also could not be obvious over Haratake, Candau, Benaiges and Sekimoto due to its dependency upon Claim 17 in addition to the other elements recited therein.

Applicants respectfully request withdrawal of the rejections.

CONCLUSION

In light of the Applicant's amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. The grounds for rejection which are not discussed herein are moot and Applicants expressly do not acquiesce in the findings not separately addressed. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

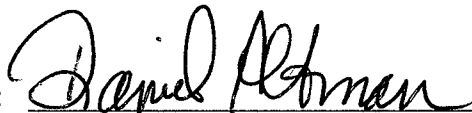
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: February 16, 2009

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